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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,774	03/22/2004	Gail K. Naughton	10557-298886	9926

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CHIEF PATENT COUNSEL
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/805,774

Applicant(s)

NAUGHTON, GAIL K.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/17/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

A preliminary amendment of 3/22/04 canceled claims 1-15 and 23-29.

Claims examined on the merits are 16-22, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

10 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of claim 16 "naturally secreted extracellular matrix" is uncertain as to meaning and scope. Being natural and secreted is relative and subjective.

20 Claim 17 is unclear as to the step that produces the composition of claim 16. If step (e) produces the composition, this should be made clear.

Claims 19 and 20 are unclear by failing to have antecedent basis for "the framework" (claim 19), and "the three-dimensional framework" (claim 20). Claim 16 on which the claims depend does not require a framework.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5 A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in 10 section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15 Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Tanagho et al (5,656,478).

The claim requires an injectable naturally secreted extracellular matrix composition for treatment of tissue defects comprising human 20 naturally secreted extracellular matrix and a pharmaceutically acceptable carrier.

Tanagho et al disclose a composition containing smooth muscle cells, extracellular matrix and a pharmaceutical acceptable carrier for injecting to grow smooth muscle tissue (col 7, lines 1-20). The 25 extracellular matrix (MatrigelTM) is inherently human naturally secreted since it is obtained from human tissue.

Tanagho et al disclose a composition as presently claimed. The claim does not exclude the smooth muscle cells in the composition of Tanagho et al.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the
10 invention was made.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanagho et al in view of Naughton et al (5,032,508), and if necessary in further view of Hansbrough et al (5,460,939) or
15 Slivka et al (5,478,739).

Claim 16 is described above.

Claims 17-20 require the extracellular matrix to be produced by culturing cells on a framework such that extracellular matrix is secreted by the cells to coat the framework, killing the cells,
20 removing cells and cellular debris, collecting the secreted extracellular matrix deposited on the framework, and processing the collected extracellular matrix with a pharmaceutical acceptable carrier. Claims 21 and 22 require the extracellular matrix to be secreted by tissue specific cells.

25 Tanagho et al is described above.

Naughton et al disclose (col 2, line 60 to col 3, line 54, paragraph bridging cols 6 and 7, col 8, line 45 to col to col 9, line 31, and col 11) culturing stromal cells comprising fibroblasts (col 9, line 15) on a framework having openings of 150-220 μm (col 11,

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lines 33-34) to form on the framework cultured cells and collagen secreted by the cells (col 11, lines 50-51 and 59-60). The cells on the framework can be separated from the framework and implanted (col 15, lines 7-15).

5 Hansbrough et al and Slivka et al disclose culturing cells on a framework to produce on the framework cells and secreted extracellular matrix similar to Naughton et al.1

It would have been obvious to produce extracellular matrix in the composition of Tanagho et al by culturing cells on a framework to
10 secrete the extracellular matrix on the framework as suggested by Naughton et al, and if needed Hansbrough et al or Slivka et al, and after separating cells from the framework as disclosed by Naughton et al, recovering the extracellular matrix for use as the extracellular matrix of Tanagho et al. It would have been obvious to kill the cells
15 before their removal from the framework when the cells are discarded and not used for implanting. The conditions of dependent claims 18-22 would have been obvious from the same type of conditions disclosed by Naughton et al, and if needed by Hansbrough et al or Slivka et al.

Double Patenting

20 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory
25 obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See,
30 e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In*

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re *Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-59 of copending Application No. 10/851,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed injectable composition containing extracellular matrix would have been obvious from the composition and injectable formulation containing naturally secreted extracellular matrix of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting

Claims 16-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,284,284 B1 or claims 1-10 of U.S. Patent No. 5,830,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently

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claimed injectable composition containing extracellular matrix would have been obvious from the composition suitable for injection containing extracellular matrix produced by the method of the claims of the patents.

5 **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be
15 obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
20 [direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "DM. Naff", with a long horizontal stroke extending to the right.

David M. Naff
Primary Examiner
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DMN
1/5/07